

## REMARKS/ARGUMENTS

### 35 USC §102 (b)

Reconsideration and allowance are requested of claims 1-6, 12-17, and 19 which the Examiner has rejected under 35 USC § 102(b) as being anticipated by Allen.

Reconsideration and allowance are requested of claims 20, 26, 27, and 29 which the Examiner has rejected under 35 USC § 102(b) as being anticipated by Finger.

Reconsideration and allowance are requested of claims 20-23 and 26 which the Examiner has rejected under 35 USC § 102(b) as being anticipated by Hicks. MPEP § 706.02(b) states that a 35 USC § 102(b) rejection can be overcome by persuasively arguing that the claims are patentably distinguishable from the prior art reference, and/or by amending the claims to patentably distinguish over the prior art. Applicant contends that both Claim

Anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed.Cir.1986). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1576 (C.A. Fed. 1991).

### Allen

The Examiner rejected claims 1-6, 12-17, and 19 as being anticipated by the Allen reference. Applicant submits that Allen does not disclose an orbital implant device that

is the same shape as Applicant's claimed device. Applicant's claim 1 claims, "the implant having a quasi-spherical shape defined by an elongation of the implant toward the medial side of the posterior side."

Allen is a symmetrical semi-sphere having four blunt mounds to receive muscles. This is shown in Allen's FIGS. 3, 4, and 7 which illustrate the symmetrical and semi-spherical nature of Allen's device. The Allen device does not have any "elongations" toward its medial or posterior sides. The four mounds in Allen are symmetrical and are toward the anterior (front) side of the orbit. The mounds mate with the implant at the front of the patient's orbit as shown in Allen's FIG. 7.

In contrast, Applicant's claimed device comprises "an elongation of the implant toward the medial side of the posterior side." This is shown in Applicant's FIGS. 2 and 15 which illustrate that the posterior portion of the implant is not symmetrical as is Allen's semi-spherical device. Instead, Applicants claimed invention is elongated toward one side. The quasi-spherical (asymmetrical) shape of Applicant's claimed invention provides significant advantages over all existing technology of which Applicant is aware because it more naturally aligns with the patient's orbit which helps to prevent the implant from becoming slanted in the socket. As described in paragraph 33 of Applicant's specification:

As seen in FIG. 2, the shape of the implant 10 of the present invention is quasi-spherical in that there is some conical elongation of the sphere posteriorly P. This conical posterior P elongation is off-center toward the medial M side of the implant 10. FIG. 4 shows the positioning of the implant 10 in a patient's orbit wherein the conical elongation extends posteriorly P and medially M as the implant 10 sits in the orbit, i.e., the conical elongation extends toward the back of the patient's orbit and

toward the nasal passage of the patient. This posterior P, medial M elongation helps to align the implant 10 within the patient's orbit so that the implant 10 maximizes its volume inside the vacant orbit. This volume maximization occurs because, as seen in FIG. 4, the natural shape of the orbit extends posteriorly P and medially M. In addition to filling volume in the orbit, the off-center conical elongation also helps to position the details of the anterior portion 22 in the normal direction of the iris because the conical elongation will naturally remain in the posterior P and medial M area of the orbit where it is most comfortable. This greatly reduces the possibility that the anterior portion 22 will become tilted upward and/or outward.

Applicant's claims 2, 3, and 4 further describe the shape of Applicant's claimed implant. Applicant submits that none of the cited references disclose the shape of Applicant's claimed implant. With respect to claim 2, Allen's FIGS. 3, 4, and 7 show that Allen does not disclose an off center elongation with respect to the anterior side. With respect to claim 3, Allen's FIGS. 3, 4, and 7 show that Allen does not disclose an astigmatism "defined by the medial and temporal sides being more anterior and the superior and inferior sides being more posterior." With respect to claim 4, Allen's FIGS. 3, 4, and 7 show that Allen does not disclose an astigmatism "defined by a radius which is longer toward the medial and temporal sides of the implant, and which is shorter toward the superior and inferior sides of the implant."

The Examiner has rejected claim 16 because the Examiner states that FIG. 1 of Allen discloses a visible marking. Applicant submits that Allen does not disclose a "visible marking on the implant" in Allen's FIG. 1. Applicant's claimed invention uses a marking on the implant to convey to the user the proper orientation of the implant. This is necessary because Applicant's claimed implant is not symmetrical and must be inserted into a patient's orbit in one particular orientation. In Allen, there is no need for

a visible marking on the implant because the device disclosed in Allen is symmetrical and could be inserted into a patient's orbit in one of several different orientations (as long as the mounds faced outward).

None of the cited prior art references disclose an implant "having a quasi-spherical shape defined by an elongation of the implant toward the medial side of the posterior side" as claimed in Applicant's claims. This shape of Applicant's claimed invention provides a significant advantage over all prior art of which application is aware. Therefore, Applicant submits that claim 1 and all of its dependent claims are allowable over the cited prior art references.

#### Finger

The Examiner rejected claims 20, 26, 27, and 29 as being anticipated by Finger. Applicant submits that claim 20 is distinguishable from Finger because Applicant's claim 20 claims "wherein the anterior portion and the posterior portion are manufactured as two separate parts and then combined together before being placed into the patient's orbit." While Finger does disclose an orbital implant comprised of several different sections, it does not disclose that the implant is divided between an "anterior portion" and a "posterior portion," i.e. a front and a back with respect to the patient's orbit.

Applicant's claim 29 claims "the implant has a quasi-spherical shape defined by an elongation of the implant toward the medial side of the posterior side." This is best seen in Applicant's FIGS. 2 and 15 and discussed above with respect to the Allen reference. Finger discloses that different sections 16 of his device may have different

expansive qualities (Finger Col. 4, lines 57-61). However, as shown in Finger's FIG. 5, this results in only one (or more) section(s) 16 being larger than the other sections. Finger does not disclose "an elongation of the implant toward the medial side of the posterior side" as claimed in Applicant's claim 29. Therefore, it is difficult or impossible for the Finger device to align with the natural shape of a patient's orbit. In contrast, the shape of Applicant's claimed invention is allowed to take advantage of the natural shape of a patient's orbit as shown in Applicant's FIG. 4.

#### Hicks

The Examiner rejected claims 20-23 and 26 as being anticipated by Hicks. Applicant respectfully submits that claims 21-23 and 26 are not anticipated by Hicks because Hicks does not disclose tunnels or chimneys. Hicks discloses a soft spongy implant. (See Hicks Col. 6, lines 35-47 and Col. 6, lines 60-65). There are no tunnels or chimneys in Hicks as claimed in Applicant's claims 21-23, instead, in Hicks the "muscles are sutured directly into the sponge" and "the spongy consistency . . . permits cell ingrowth from extrinsic muscles and from connective tissues." (See Hicks Co. 6, lines 41 and Col. 6, line 45).

Further, with respect to claim 26, Applicant has analyzed and performed a literal word search of Hicks and could not find that Hicks discloses an Acrylic implant. In fact, the soft spongy implant of Hicks teaches away from the hard acrylic implant claimed in Applicant's claim 26.

For these reasons, Applicant submits that claims 21-23 and 26 are allowable over Hicks.

35 USC § 103(a)

Reconsideration and allowance are requested of claims 7-8 and 20-29 which the Examiner has rejected under 35 USC § 103(a) as being obvious over Allen in view of Kelman and/or Hicks. Reconsideration and allowance are requested of claims 9-10 which the Examiner has rejected under 35 USC § 103(a) as being obvious over Allen in view of Finger. Reconsideration and allowance are requested of claim 28 which the Examiner has rejected under 35 USC § 103(a) as being obvious over Finger in view of Kelman. Applicant has cancelled claim 18.

A *prima facie* case of obviousness requires (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, (2) there must be a reasonable expectation of success, and (3) the prior art references must teach or suggest all the claim limitations. In re Sang-Su Lee, 277 F.3rd 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002) (and cases cited therein). The U.S. Supreme Court stated in KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007) that the factors in Graham v. John Deere Co., 383 U.S. 1 (1966) should be considered in the determination of obviousness. The four Graham factors are: (A) Determining the scope and contents of the prior art; (B) Ascertaining the differences between the prior art and the claims in issue; (C) Resolving the level of ordinary skill in the pertinent art; and (D) Evaluating evidence of secondary considerations. Applicant respectfully submits that a *prima facie* case has not been established.

### Claim 7

Applicant submits that a *prima facie* case of obviousness has not been established for claim 7. Claim 7 has been amended to depend from claim 1 instead of claim 6. Claim 7 has also been amended to recite that there are openings (tunnels and/or chimneys) in both the first portion and second portions of the implant and that these openings align when the two portions of the implant are combined together.

One major disadvantage with prior art implants was that openings had to be drilled into the orbital implant after the implant was manufactured. Applicant's invention as claimed in claim 7 provides that the implant is manufactured in two separate parts (i.e. by injection molding) with openings formed in the implant at the time the two parts are manufactured. Both parts of the implant can be created with openings, then, when the two parts are put together, the openings of each part are combined. (See paragraph 51 of Applicant's Specification; See Also Applicant's FIGS. 1, 16 and 17). This eliminates the need to drill openings into the implant after it is manufactured.

### Claim 18

Claim 18 has been cancelled.

### Claims 24 and 25

Applicant has rewritten claims 24 and 25 in independent format. Applicant submits that a *prima facie* case of obviousness has not been established for these claims. Claims 24 and 25 claim an orbital implant that is "manufactured as two separate parts and then combined together before being placed into the patient's orbit . . . ." Further,

these claims state that there are a finite number of openings (tunnels and/or chimneys) in both the first portion and the second portion of the implant and that these openings align when the two parts are combined together.

The limitations of Applicant's claims 24 and 25 are not contained in the cited prior art. Applicant's claims 24 and 25 represent a significant advancement in orbital implant technology that is markedly different than any of the cited prior art. One of the major disadvantages with prior art implants was that openings had to be drilled into the orbital implant after the implant was made. Applicant's invention as claimed in claims 24 and 25 allows an implant to be manufactured in two separate parts (i.e. by injection molding) with the openings formed in the implant at the time the two parts are manufactured. Both parts of the implement can be created with openings, then, when the two parts are put together, the openings of each part are combined. (See paragraph 51 of Applicant's Specification; See Also Applicant's FIGS. 1, 16 and 17). This eliminates the need to drill openings into the implant after it is manufactured.

#### Secondary Considerations

A further area of consideration in the determination of obviousness involves the analysis of the four factors laid out in Graham v. John Deere Co., 383 US 1 (1966). Of those four factors the secondary considerations are generally considered the most important items of evidence available. Simmons Fastener Corp. v. Illinois Tool Works, 739 F.2d 1573, 1575 (Fed. Cir. 1984). Applicant submits there has been a long felt but unsatisfied need for the invention. The prior art traditionally used spherical implants. Then, in the 1960s Allen created his semi-spherical implant. Most doctors, however,



were reluctant to use the Allen implant because they were conditioned to use spherical implants whereas the Allen device had a semi-circular shape with four blunt mounds. Applicant's claimed invention provides a quasi-spherical implant which avoids the problems associated with pure spheres (i.e. rotation of the prosthesis and the lack of motility due to very little traction from a pure sphere) without resorting to the extreme semi-sphere shape of the Allen implant.

The present invention also helps the orbital implant properly align within the orbit because of its claimed unique shape. Its unique shape fills more of the socket and helps improve frontal placement of the anterior details so the details are not tilted outwardly as often seen with most front detailed implants.

The present invention also provides openings (tunnels and/or chimneys) in the implant without having to drill holes into the implant by creating the implant in two separate portions, each portion having a number of openings, then combining the two portions to create openings through the implant.

#### Impermissible Hindsight

Applicant respectfully submits that the Examiner engaged in impermissible hindsight reconstruction in combining the references, based upon the benefits of the invention. Applicant believes that at the time the invention was made, there was no indication whatsoever in the prior art that would suggest to one having ordinary skill in the art to combine Allen with Kelman, Hicks, or Finger. There was no indication whatsoever in the prior art to arrive at the invention Applicant has claimed in claims 24 and 25 which claim an implant "manufactured as two separate parts", each part having

a finite number of openings so that when the parts are combined the openings are in alignment.

#### **Allowable Subject Matter – New Claim 30**

The Examiner has indicated that claim 11 is allowable if rewritten in independent form. Applicant has rewritten claim 11 as new claim 30 including the limitations of the base claim and all intervening claims. (Applicant notes that the Examiner states in the 3/18/2008 Office Action that claim 11 would be allowable “if rewritten to overcome the rejection(s) under 35 USC 112, 2<sup>nd</sup> paragraph, set forth in this Office action . . . .” However, the Examiner has not set forth any 35 USC 112, 2<sup>nd</sup> paragraph rejections in this Office action. Therefore, Applicant assumes this statement was made by the Examiner inadvertently).

#### **New Claim 31**

Applicant respectfully requests allowance of new claim 31.

#### **Claims Not Discussed Herein**

Applicant submits that the claims not specifically discussed herein depend from claims discussed herein and are therefore allowable for the same reasons.

#### **Conclusion**

It is respectfully submitted that this response places Applicant’s application in condition for allowance, and therefore further and favorable action on this application is requested. If for any reason the Examiner has any questions about these claims, Applicant's attorney respectfully requests the Examiner to contact Applicant's attorney

by telephone to set up an interview. It is believed that such an interview will be helpful in placing the application in condition for allowance.

Respectfully submitted,

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